

REMARKS

Applicants have concurrently filed a Request for Continued Examination and, therefore, respectfully request consideration of the above amendments and following remarks prior to further examination of the present application.

Claims 3 and 30-32 are pending in the present application. Claim 3 is amended herein. Claims 1, 2, 4-6, 24-29 and 33-35 have been canceled. Favorable consideration of the pending claims is respectfully requested.

Applicants' Response to Objections to the Claims

In the Office Action, the Examiner objected to claims 27-35 under 35 U.S.C. §132(a) as allegedly introducing new matter. Applicants have canceled claims 27-29 and 33-35. With regard to claims 30-32, Applicants respectfully submit that the subject matter contained in these dependent claims is generally supported throughout the specification, particularly paragraphs 31 and 39 of the specification, as well as Example 4. Accordingly, Applicants respectfully request reconsideration and withdrawal of the objection to claims 30-32.

Applicants' Response to 35 U.S.C. §112, Second Paragraph Rejection

Claims 26-35 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. In particular, the Examiner asserts that claim 26 recites adding a solvent in step (iii) and adding a solvent in step (iv), and that it is not apparent whether these are the same or different solvents.

Applicants have canceled claim 26 herein. The subject matter of claim 26, however, has been added into independent claim 3. By the amendment to claim 3, Applicants have clarified that the solvent added in each of these steps is a "buffer" and that it is the same "buffer" in each step. In view thereof, Applicants respectfully submit that the Section 112, second paragraph, rejection has been overcome.

Applicants' Response to 35 U.S.C. §102(e) and §103 Rejections over Cima

Claims 1-6 and 24-25 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent Publication No. 2002/0048610 A1 to Cima et al. (hereinafter "Cima"). Claims 24-35 are rejected under 35 U.S.C. §103 as allegedly being obvious over Cima. Applicants have canceled claims 1, 2, 4-6, 24-29 and 33-35. Applicants respectfully

request reconsideration on the basis that Cima fails to disclose or suggest each and every element of Applicants' independent claim 3, as amended herein, and thus claims 30-32 which depend therefrom.

The Examiner asserts that Cima teaches a method for determining how the solubility, dissolution or stability of polymorphs depend on the solid form by preparing an array of samples with a controlled amount of the compounds-of-interest, forming a liquid portion by adding a solvent and determining how much compound-of-interest is dissolved in the liquid portion depending on its form. The Examiner concludes that Cima's disclosure covers the subject matter of Applicants' claims.

Applicants have amended independent claim 3 to further define the invention. Applicants have added the subject matter recited in dependent claim 26, as well as several additional method steps and recitations into independent claim 3. The amendments are supported by the dissolution assay described in Example 4 of the present application, as well as with reference to Figure 6.

More specifically, amended claim 3 is directed to a specific method of determining how the dissolution of a solid compound-of-interest is affected by its physical or chemical form as a function of time. The claim requires a number of steps, which are exemplified by the dissolution assay described in Example 4 and depicted in Figure 6, including:

- preparing a first sub-array of samples, each comprising a controlled amount of the compound-of-interest in a first form;

- preparing at least a second sub-array of samples, each comprising a controlled amount of the compound-of-interest in a second form that differs in its physical or chemical form from the first form;

- forming a liquid portion of each sample in the first sub-array by adding a controlled amount of a buffer to each sample in the first sub-array at a time point that is unique to each sample in the first sub-array;

- forming a liquid portion of each sample in the second sub-array by adding a controlled amount of the buffer to each sample in the second sub-array at a time point that is unique to each sample in the second sub-array but is the same as one of the time points at which the buffer was added to one of the samples in the first sub-array;

- mixing and incubating each sample in the first and second sub-arrays;

separating the liquid portion of each sample in the first and second sub-arrays from any solid portion each sample may contain at a time point that is the same for each sample in the first and second sub-arrays;

measuring the final pH of the liquid portion of each sample in the first and second sub-arrays;

diluting the liquid portion of each sample in the first and second sub-arrays; and

determining how much compound-of-interest dissolved in the liquid portion of each sample to provide dissolution data for each form of the solid compound-of-interest as a function of time.

This specific method for performing a dissolution assay is not disclosed or suggested in Cima. Although Cima contains a general teaching of dissolution assays, it fails to disclose or suggest all of the specifically recited steps of the presently claimed assay. In particular, there is no teaching in Cima to have different samples in an array with different time points for purposes of measuring and establishing a dissolution profile as a function of time. Cima additionally fails to disclose or suggest a number of other steps recited in the claim, including the steps of adding the same buffer to all of the samples in the array, mixing and incubating the samples, determining the final pH of the liquid portion and diluting the liquid portions prior to determining dissolution. These steps all form part of the specific dissolution assay methodology exemplified in Applicants' Example 4.

In the Office Action, the Examiner asserts that Applicants' previous claim 26 was obvious in view of Cima's disclosure of sampling the dissolution medium of each array element versus time. According to the Examiner, it would have been obvious for one of ordinary skill in the art "to replace measurement of the dissolved form in the same sample at certain time intervals with an equivalent measurement of the dissolved form in the array of equivalent samples at certain time point for each sample, because this yields the same results and is more convenient." Cima's general disclosure regarding dissolution assays, however, would not have suggested Applicants' different technique, nor the specific combination of steps recited in Applicants' amended claim 3. The measurement of various samples representing different time points is a distinctly different manner of obtaining dissolution data. It can be done simultaneously for multiple forms of the solid compound-of-interest by using sub-arrays within an array, as recited in Applicants' claim. Cima does not contain any suggestion of such a methodology. Moreover, there would be no apparent reason for one of

ordinary skill in the art to attempt to develop Applicants' specific dissolution assay from the general teachings of Cima. Applicants recited method is directed to an assay designed to assess how the dissolution of a solid compound is affected by its different physical or chemical forms, and how pH affects the dissolution profile of these different forms. More specifically, a buffer is used in the recited method to determine the effects of pH on the dissolution profile of each form. The specifically recited method steps of Applicants' claim are all required to achieve the dissolution data as a function of time to determine how the dissolution of a certain solid compound is affected by its form and how each form is affected by pH. It would not have been obvious to one of ordinary skill in the art, in view of Cima's generic disclosure, to arrive at all of Applicants' specifically recited steps to determine how the dissolution of a solid compound-of-interest is affected by its form.

In view of the foregoing amendments and remarks, Applicants respectfully submit that claim 3, and thus claims 30-32 which depend therefrom, are patentable over Cima. Reconsideration and withdrawal of the Section 102 and 103 rejections over Cima is respectfully requested.

CONCLUSION

The Commissioner is hereby authorized to charge any deficiency or credit any overpayments necessitated by this Amendment to Deposit Account No. 10-0750/TPI5020USPCT1.

Early favorable action on the merits is respectfully requested.

Respectfully submitted,

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Dated: August 12, 2009

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